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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,603	09/05/2003	Robert G. Turcott	A03P3003-US1	7981

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/656,603		TURCOTT, ROBERT G.	
	Examiner		Art Unit	
	Carl H. Layno		3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-25 and 30-34 is/are allowed.
- 6) ☒ Claim(s) 1,5-7,15-19 and 26-29 is/are rejected.
- 7) ☒ Claim(s) 2-4,8-14 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/16/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449), which was received by the Office on September 16, 2003.

Drawings

2. The drawings are objected to because they appear to be informal and have the following minor informalities:

-Fig.6, the labels "690" and "630" (as enumerated in the specification) appear to read as "890" and "830", respectively.

Additionally, the labels for Figs.2, 3A, 3B, 5, 6, 8, 9, 10, 11, 12A, and 13A appear to be informal.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

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application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 26, line 2 recites the phrase "said ...second hemodynamic signals". This term has no antecedent basis. To overcome this rejection, the Examiner suggests replacing this with the term "said...new hemodynamic signals", which has basis in independent claim 25.

Claims 27-29 are also rejected since they depend from rejected claim 26.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

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patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 5-7, 15, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Hartley et al (US 2003/0105499 A1).

In regard to claims 1 and 15, the Hartley et al (US 2003/0105499 A1) patent describes an implantable rate adaptive cardiac rhythm management device **100** (Fig.1) whose operation reads upon the applicant's claimed method steps. Specifically, Hartley et al receives hemodynamic low frequency signals through electrodes **120** and **145** (Fig.4), these signals are filtered by bandpass filter **420** (p.7, paragraph [0067]). The resultant signal is used to calculate a minute ventilation **440** parameter, which controller **165** uses to adjust the rate of delivery of cardiac rhythm management therapy, such as pacing (p.4, paragraph [0039], lines 10-20). See also p.8, paragraph [0078], lines 5-8. The sampling of the detected low frequency data using a well known sampling rate, such as the Nyquist rate, using A/D converter **425** (Fig.4) would be inherent in the proper operation of the device.

In regard to claims 5-7, the low frequency signal monitored by Hartley et al is in the range of 0.1Hz to 2.0 Hz (p.7, paragraph [0067], lines 2-3).

In regard to claim 17, the Hartley et al device includes a low pass filter **435** (Fig.4) with a cutoff frequency of approximately 1 Hz for heart rate signals greater than 88 bpm (see Table 1 on p.8).

7. Claims 1, 5, 6, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt et al (US 6,096,061) or Alt (US 5,044,366).

The Alt et al (US 6,096,061) patent describes a implantable defibrillator **10** (Figure) whose elements perform applicant's claimed method steps. The Alt et al defibrillator detects body movement signals associated with the exercise of a patient using an activity sensor **30** and complementary sensor **14**. The sensed signals are filtered through a low frequency narrow bandpass filter **31** (col.3, lines 36-43) then processed through evaluation circuit **32**. If the processed signal exceeds a "first threshold", the pacing rate is increased (col.9, lines 27-32). The sampling of the detected low frequency data using a well known sampling technique, such as sampling at the Nyquist rate, would be inherent in the proper operation of the device.

The Alt (US 5,044,366) patent describes an implantable cardiac pacemaker having similar features as the Alt et al '061 patent, above, and performing the same functions. The Alt '366 device (Fig.1) includes activity sensor **3**, a complementary sensor **7**, an evaluation circuit **10b**, a logic circuit **12**, a rate control circuit **21**, and a lowpass filter circuit (Fig. 2a). The pacing rate of Alt is adjusted based upon detected activity and complementary sensor data (Fig.8).

In regard to claims 5 and 6, sampling the low frequency sensor signals between 0.1Hz and 1Hz would be inherent to the Alt et al '061 and Alt '366 devices since both sense signals in the range of between 0.1 Hz and 4 Hz (col.3 lines 42-44 of Alt et al '061 and Fig.2a of Alt '366).

Claim Rejections - 35 USC § 103

8. Claims 16, 18, and 19 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hartley et al (US 2003/0105499 A1).

In regard to claim 16, the elements of the cardiac rhythm management device of Hartley et al, as disclosed *supra*, are resident within a "signal processor" circuit 155 (Fig.4) (p.4,

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paragraph [0039]). To have specified that this circuit be implemented utilizing a programmable microcontroller would have been an obvious matter of design choice, if not inherent, to one of ordinary skill in the art, in order to simplify implementation of the circuit (i.e. using one IC) for use in the implantable device, given the well known versatility of microcontrollers.

In regard to claims 18 and 19, the Hartley et al device processes the hemodynamic signals sensed by electrodes 120,145 (Fig.4). Claims 18 and 19 fail to recite any additional physical structures which would further limit them, hence the rejection. The Examiner considers these claims to be “product-by-process” claims. See MPEP 2113. What is important is the hemodynamic signal produced not the different steps/details used in their production.

Allowable Subject Matter

9. Claims 26-29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
10. Claims 2-4, 8-14, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. Claims 21-25, and 30-34 are allowed.
12. The following is a statement of reasons for the indication of allowable subject matter:

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Independent claim 21 recites a method for optimizing AV delay in an implantable cardiac therapy device (ICTD) including the unusual steps of “calculating a baseline average”, “calculating a new average”, and “calculating the difference between said baseline average and said new average”. Although the Spinelli et al (US 5,466,245), cited herein by the Examiner, discloses an AV delay optimization method and apparatus, it fails to calculate averages in the manner claimed by the applicant. Consequently, the Examiner deems claim 21 and its depending claims to be allowable.

Independent claim 25 discloses a method to determine the optimum placement of pacing leads in which hemodynamic signals are used to determine pacing lead positions. Lacking prior art that reads upon these steps, the Examiner deems this claim and its depending claims to be allowable.

Independent claim 30 recites a method for optimizing pacing rate cutoff in an implantable cardiac device. Again, applicant's method utilizes steps involving the reception of hemodynamic signals not found in the prior art. Consequently, the Examiner also deems this claim and its depending claims to be allowable.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

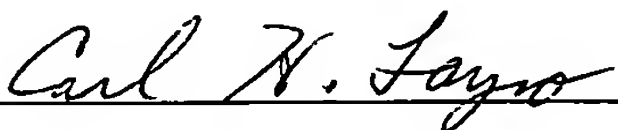
The Spinelli et al (US 5,466,245) is cited for its pertinent method for optimizing AV delays in an implantable pacemaker.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on 9/4/5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



CARL LAYNO
PRIMARY EXAMINER

CHL
5/1/2006